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| EXAMINER | |
|---|---|
| STEADMAN, DAVID J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1652 | |

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/625,790 | PELTZ ET AL. | |
| | Examiner | Art Unit | |
| | David J Steadman | 1652 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-7 and 32-56* is/are pending in the application.

4a) Of the above claim(s) *7,33,35-43,48-50,52 and 54-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,32,34,44-47,51 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of the Application*

**[1]** Claims 1-7 and 32-56 are pending in the application.

**[2]** Applicants' amendment to the claims, filed August 13, 2004, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

**[3]** Applicants' amendment to the specification, filed August 13, 2004, is acknowledged.

**[4]** Receipt of a substitute sequence listing in computer readable form, a paper copy thereof, a statement of their sameness, and a statement that the substitute paper copy of the sequence listing includes no new matter, all filed August 13, 2004, is acknowledged.

**[5]** Applicants' arguments filed on August 13, 2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

**[6]** The text of those sections of Title 35, U.S. Code not included in the instant action can be found in a prior Office action.

### *Election by Original Presentation*

**[7]** Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-6, 34, 44-47, 51, and 53, drawn to a method for treating disorders associated with the activities of a eukaryotic peptidyl transferase

center or a method for inhibiting the function of a eukaryotic peptidyl transferase center by administering a drug which decreases the efficiency of –1 ribosomal frameshifting, wherein the drug includes an antibiotic, classified in class 514, subclass 789.

II. Claims 2-6, 33, 44-47, and 51-53, drawn to a method for treating disorders associated with the activities of a eukaryotic peptidyl transferase center or a method for inhibiting the function of a eukaryotic peptidyl transferase center by administering a drug which increases the efficiency of –1 ribosomal frameshifting, wherein the drug includes an antibiotic, classified in class 514, subclass 789.

III. Claims 3, 5-6, 34, 37, 44-47, 51, and 53, drawn to a method for treating disorders associated with the activities of a eukaryotic peptidyl transferase center or a method for inhibiting the function of a eukaryotic peptidyl transferase center by administering a drug which decreases the efficiency of –1 ribosomal frameshifting, wherein the drug includes a drug that interacts with a protein encoded by a *mof4-1*, *mof2-1*, or *mof5-1* gene or human homologues thereof, classified in class 514, subclass 789.

IV. Claims 3, 5-6, 33, 37, 44-47, and 51-53, drawn to a method for treating disorders associated with the activities of a eukaryotic peptidyl transferase center or a method for inhibiting the function of a eukaryotic peptidyl transferase center by administering a drug which increases the efficiency of –1 ribosomal frameshifting, wherein the drug includes a drug that

interacts with a protein encoded by a *mof4-1*, *mof2-1*, or *mof5-1* gene or human homologues thereof, classified in class 514, subclass 789.

V. Claims 3, 5-6, 34, 38, 44-47, 51, and 53, drawn to a method for treating disorders associated with the activities of a eukaryotic peptidyl transferase center or a method for inhibiting the function of a eukaryotic peptidyl transferase center by administering a drug which decreases the efficiency of –1 ribosomal frameshifting, wherein the drug includes a polypeptide of a ribosome binding protein, L3, classified in class 514, subclass 2.

VI. Claims 3, 5-6, 33, 38, 44-47, and 51-53, drawn to a method for treating disorders associated with the activities of a eukaryotic peptidyl transferase center or a method for inhibiting the function of a eukaryotic peptidyl transferase center by administering a drug which increases the efficiency of –1 ribosomal frameshifting, wherein the drug includes a polypeptide of a ribosome binding protein, L3, classified in class 514, subclass 2.

VII. Claims 3, 5-6, 34, 39-47, 51, and 53, drawn to a method for treating disorders associated with the activities of a eukaryotic peptidyl transferase center or a method for inhibiting the function of a eukaryotic peptidyl transferase center by administering a drug which decreases the efficiency of –1 ribosomal frameshifting, wherein the drug includes a vector, classified in class 514, subclass 44.

VIII. Claims 3, 5-6, 33, 38, 44-47, and 51-53, drawn to a method for treating disorders associated with the activities of a eukaryotic peptidyl transferase

center or a method for inhibiting the function of a eukaryotic peptidyl transferase center by administering a drug which increases the efficiency of –1 ribosomal frameshifting, wherein the drug includes a vector, classified in class 514, subclass 44.

IX. Claims 2-4, 7, 35-36, 48-51, and 54-56, drawn to a method for treating disorders associated with the activities of a eukaryotic peptidyl transferase center or a method for inhibiting the function of a eukaryotic peptidyl transferase center by administering a drug which modulates nonsense-mediated mRNA decay, wherein the drug includes an antibiotic, classified in class 514, subclass 789.

X. Claims 3, 7, 35-37, 48-51, and 54-56, drawn to a method for treating disorders associated with the activities of a eukaryotic peptidyl transferase center or a method for inhibiting the function of a eukaryotic peptidyl transferase center by administering a drug which modulates nonsense-mediated mRNA decay, wherein the drug includes a drug that interacts with a protein encoded by a *mof4-1*, *mof2-1*, or *mof5-1* gene or human homologues thereof, classified in class 514, subclass 789.

XI. Claims 3, 7, 35-36, 38, 48-51, and 54-56, drawn to a method for treating disorders associated with the activities of a eukaryotic peptidyl transferase center or a method for inhibiting the function of a eukaryotic peptidyl transferase center by administering a drug which modulates nonsense-

mediated mRNA decay, wherein the drug includes a polypeptide of a ribosome binding protein, L3, classified in class 514, subclass 2.

XII. Claims 3, 7, 35-36, 39-43, 48-51, and 54-56, drawn to a method for treating disorders associated with the activities of a eukaryotic peptidyl transferase center or a method for inhibiting the function of a eukaryotic peptidyl transferase center by administering a drug which modulates nonsense-mediated mRNA decay, wherein the drug includes a vector, classified in class 514, subclass 44.

**[8]** Newly submitted claims 7, 33, 35-43, 48-50, 52, and 54-56 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the inventions of Groups I-XII are independent because the methods of Groups I-XII utilize different products, *i.e.,* drugs, and yield different results. Further, Groups I-XII have a separate status in the art and require a separate search based on recited limitations in the claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 7, 33, 35-43, 48-50, 52, and 54-56 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

**[9]** Claim 1 link(s) inventions I-XII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions

shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.

**[10]** Claim 32 link(s) inventions I-VIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 32. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.

**[11]** Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

**[12]** It is noted that applicants' arguments support the independent or distinct inventions and further support a separate search for the independent or distinct inventions, *i.e.,* the inventions of Groups I-XII, as listed above. In view of applicants' arguments and upon reconsideration of the restriction requirement, the examiner withdrew the restriction requirement as set forth in the Office action mailed February 05, 2004 as it appeared to the examiner that the claims were not patentably distinct and the

search for each invention would be co-extensive. The examiner's position was based on applicants' assertion that "the common part of the invention is that of affecting the function of the peptidyl transferase center with the drug" (p. 3 of the response filed March 08, 2004) and the failure of the evidence of record to exclude or differentiate a viral infection from those diseases that are "associated with a nonsense mutation in a gene modulating the function of a eukaryotic peptidyl transferase" as recited in original claim 7 (as evidenced by the examiner's stated interpretation of the term as encompassing viral infection or HIV (see item [7], part [b] of the Office action mailed May 14, 2004). However, the claims have been amended to add claims reciting distinct drugs that can be used in the claimed methods, *i.e.,* an antibiotic, a drug that interacts with a protein encoded by a *mof4-1*, *mof2-1*, or *mof5-1* gene or human homologues thereof, a polypeptide of a ribosome binding protein, L3, or a vector. Further, applicants now make clear that the scope of diseases that are "associated with a nonsense mutation" excludes viral infection (it should be noted that claim 7 now recites "a disease resulting from a nonsense mutation in a gene") and the claims have been amended to recite specific diseases that are treated by the methods. Applicants argue that the examiner's interpretation of the term is incorrect as viral infection and HIV are not intended to be encompassed by amended claim 7, which now recites "a disease resulting from a nonsense mutation." Applicants argue that viral infection arises from ribosomal frameshifting not from a nonsense mutation, which results in diseases such as those recited in claim 50 (page 12, middle, response filed August 13, 2004). Thus, applicants make clear that the diseases "resulting from a nonsense mutation in a gene"

are distinct from those that result from ribosomal frameshifting. It should be noted that the specification fails to expressly exclude viral infections from those disease that are considered to be "associated with a nonsense mutation" as recited in original claim 7. Although original claim 7 was co-examined with claims 1-6 in the Office action mailed May 14, 2004, the co-examination was based on inclusion of a viral infection being encompassed by a "disease associated with a nonsense mutation." As such, claims 5-6 were examined/searched as being "species" of claim 7. Thus, if the examiner found art that anticipated/made obvious claims 5-6, the same art would also anticipate/make obvious the broader "genus" claim 7. However, in view of applicants' arguments and amendment to claim 7, this is no longer the case as art that anticipates/makes obvious claims 5-6 would not, according to applicant's arguments and in view of the claim amendment, anticipate/make obvious claim 7. As such, claim 7 has been withdrawn as being drawn to a non-elected invention.

In the interest of advancing prosecution, the examiner has attempted to group the claims according to the drug type, *i.e.,* antibiotic, drug that interacts with a protein encoded by a *mof4-1*, *mof2-1*, or *mof5-1* gene or human homologues thereof, a polypeptide of a ribosome binding protein, L3, or a vector, and the action of the drug, *i.e.,* increases or decreases efficiency of –1 ribosomal frameshifting or modulates nonsense-mediated mRNA decay.

***Specification/Informalities***

**[13]** In view of applicants' amendment to the specification, the objections to the specification as set forth at items [3] and [6] of the Office action mailed May 14, 2004, are withdrawn.

**[14]** The objection to the specification as set forth at item [4] of the Office action mailed May 14, 2004 is maintained for the reasons of record and the reason(s) stated below.

**[15]** RESPONSE TO ARGUMENTS: Applicants argue the objection has been overcome by amendment. Applicants' argument is not found persuasive.

While the amendment makes specific reference to the prior applications, the status (abandoned) of the nonprovisional parent application has not been updated. Appropriate correction is required.

**[16]** The objection to the specification as set forth at item [5] of the Office action mailed May 14, 2004 is maintained for the reasons of record and the reason(s) stated below.

**[17]** RESPONSE TO ARGUMENTS: Applicants argue the objection has been overcome by amendment. Applicants' argument is not found persuasive.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. To be in compliance, applicants should identify nucleotide sequences of at least 10 nucleotides in the specification by a proper sequence identifier, i.e., "SEQ ID NO:" (see MPEP 2422.01). Sequences disclosed in Figures 1A and 1B

have not been identified by a sequence identifier. If these sequences have not been listed in the computer readable form and paper copy of the sequence listing, applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification, and a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d). Appropriate correction is required.

***Claim Rejections - 35 USC § 112, Second Paragraph***

**[18]** The rejection of claims 1-4 and new claims 32, 34, 44-47, 51, and 53 under 35 U.S.C. 112, second paragraph, as set forth at item [7] of the Office action mailed May 14, 2004 is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENTS: Addressing the rejection set forth at item [7], part [a] of the Office action mailed May 14, 2004, applicants argue the rejection is overcome by amendment to recite the result or outcome is "one of the therapeutic effect of the drug on the patient" and that the therapeutic effect is "that of modulating programmed ribosomal frameshifting and/or nonsense-mediated mRNA decay." Applicants' argument is not found persuasive.

The claimed method remains incomplete as it is unclear as to those disorders that are intended to be encompassed by the term "disorders associated with the activities of a eukaryotic peptidyl transferase center," it is unclear as to how one

determines whether a patient is in need of a drug which modulates programmed ribosomal frameshifting and/or nonsense-mediated mRNA decay," and it is unclear as to a "therapeutically effective amount of a drug which modulates programmed ribosomal frameshifting." It is suggested that applicants clarify the scope of disorders and patients that are to be included within the scope of the claim and clarify the amount of drug that is considered to be effective for modulating programmed ribosomal frameshifting. It is noted that claims 5-6 clarify claim 1 as to the scope of disorders/patients to be treated and is definite as the effective amount of the drug is an amount that will treat viral infection or HIV.

**[19]** In view of the withdrawal of claim 7 from further consideration, applicants' arguments addressing the rejection set forth at item [7], part [b] of the Office action mailed May 14, 2004, is rendered moot.

**[20]** Claim(s) 51 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is necessitated by amendment.

Claim 51 (claim 53 dependent therefrom) is indefinite in the recitation of "an effective amount of drug" and "a sufficient time to change the efficiency of –1 ribosomal frameshifting." It is unclear from the claims and the specification as to an amount of drug that is intended to be effective and the period of time that will change the efficiency of –1 ribosomal frameshifting. It is suggested that applicants clarify the meaning of the claim.

***Claim Rejections - 35 USC § 112, First Paragraph***

**[21]** The written description rejection of claim(s) 1-3, 5, 32, 34, 44-46, 51, and 53 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth at item [8] of the Office action mailed May 14, 2004 and for the reasons stated below.

**[22]** RESPONSE TO ARGUMENTS: It is noted that applicants do not separately address the written description and scope of enablement rejections and instead address the rejections in a single response. To the extent applicants' arguments appear to address the instant rejection, applicants' arguments are addressed herein. Applicants argue the disclosure is not limited to anisomycin and sparsomycin as drugs as the specification teaches several examples of drugs, that include but are not limited to antibiotics, *e.g.,* L3 ribosomal binding protein and an expression vector. Applicants' argument is not found persuasive.

The specification fails to provide a representative number of species of "drugs" as encompassed by the claims sufficient to show that applicants were in possession of the claimed invention. Even in view of the additional representative examples of alleged "drugs," *i.e.,* L3 ribosomal binding protein and expression vectors, these representative examples fail to represent the entire genus. The genus of recited "drugs" encompasses a genus that is *widely variant*, including drugs having any structure and any function that "modulates programmed ribosomal frameshifting and/or nonsense-mediated mRNA decay." That the genus encompasses widely variant species with respect to structure and function of the drug as asserted by the examiner in a previous Office action is

undisputed by applicants. In this case, the disclosed representative species fail to represent the entire genus of "drugs" as encompassed by the claims. See particularly MPEP § 2163.

**[23]** The scope of enablement rejection of claims 1-6, 32, 34, 44-47, 51, and 53 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth at item [9] of the Office action mailed May 14, 2004 and for the reasons stated below.

**[24]** RESPONSE TO ARGUMENTS: It is noted that applicants do not separately address the written description and scope of enablement rejections and instead address the rejections in a single response. To the extent applicants' arguments appear to address the instant rejection, applicants' arguments are addressed herein. Applicants argue the disclosure is not limited to the working examples of anisomycin and sparsomycin as drugs as additional working examples of drugs, *i.e.,* L3 ribosomal binding protein and expression vectors, are disclosed in the specification. Applicants further argue that the specification supports in vivo as well as in vitro methods, citing pp. 16, 37-38, 59-60 and Figure 8 as allegedly enabling a skilled artisan to practice the full scope of claimed methods *in vivo*. Applicants argue successful treatment of humans or animals is not required for patentability. Applicants' arguments are not found persuasive.

While additional examples of "drugs," *i.e.,* L3 ribosomal binding protein and expression vectors, may be disclosed in the specification, the specification fails to enable the full scope of the claims. As written, the claims are so broad as to encompass *in vivo* methods of treating a vast number of diseases using any drug that "modulates

programmed ribosomal frameshifting and/or nonsense-mediated mRNA decay."

Although the specification fails to teach even a single working example of the claimed method of treatment in a patient, the prior art enables a method for *in vivo* treatment of HIV infection using anisomycin (see Japanese Patent JP 63146818 A). It is noted that neither the specification nor the prior art teaches *in vivo* methods of treating a patient by expression of an L3 ribosomal binding protein or expression vectors as encompassed by the claims and further fails to teach *in vivo* methods of treating any of the diseases as set forth in claim 50 using an antibiotic, particularly anisomycin and sparsomycin, an L3 polypeptide, or expression vectors. It should also be noted that applicants' cited guidance for practicing the method *in vivo* should not be confused with guidance for practicing the claimed methods in a patient. Regarding gene therapy, one of skill in the art is well aware that the use of gene therapy as a therapeutic treatment is highly unpredictable. For example, Dang et al. (*Clin Can Res* 5:471-474), in a report summarizing the status of gene therapy disclose, "The obstacles surrounding effective human gene therapy have been studied by the Orkin-Motulsky Committee commissioned by Dr. Harold Varmus, director of the NIH (Bethesda, MD). This committee found human gene therapy to be an immature science with limited understanding of gene regulation and disease models for pre-clinical studies" (page 471, left column, middle). Furthermore, Fox (*Nat Biotechnol* 21:217), citing a finding that gene therapy for treatment of X-SCID has been correlated with incidence of leukemia, suggests that even gene therapy that successfully achieves a therapeutic effect may have unpredictable deleterious side effects. Applicants statement regarding no

requirement to provide evidence of actual success in treating humans or animals for patentability is acknowledged. However, applicants are required to demonstrate that the specification in view of the prior art enables the full scope of the claims. It is the examiner's position that, when the scope of the claimed invention and the enablement provided by the specification/prior art is subjected to the analysis of the Factors of *In re Wands* (see particularly pp. 8-10 of the Office action mailed May 14, 2004), applicants' specification in view of the prior art fails to achieve a level of enablement that would allow a skilled artisan to practice the full scope of the claimed invention.

***Claim Rejections - 35 USC § 102***

**[25]** In view of the amendment to the claims, the rejection of claims 1-4 under 35 U.S.C. 102(b) as being anticipated by Carrasco et al. as set forth at item [10] of the Office action mailed May 14, 2004, is withdrawn.

**[26]** The rejection of claims 1-5, 32, 34, 44-46, 51, and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Japanese Patent JP 63146818 A as evidenced by Dinman et al. is maintained for the reasons of record as set forth at item [11] of the Office action mailed May 14, 2004 and for the reasons stated below.

**[27]** RESPONSE TO ARGUMENTS: Applicants argue JP 63146818 A fails to teach or suggest administering a drug so as to specifically affect ribosomal frameshifting and/or nonsense-mediated mRNA decay. Applicants further argue that Dinman et al. was published after the earliest effective filing date of the instant application and cannot be used against the present claims. Applicants' argument is not found persuasive.

In response to applicants' argument that JP 63146818 A fails to teach or suggest administering a drug so as to specifically affect ribosomal frameshifting and/or nonsense-mediated mRNA decay, it is noted that there is no requirement in claim 1 that the administered drug actually affect programmed ribosomal frameshifting and/or nonsense-mediated mRNA decay. In this case, the active step of claim 1 is merely administering "a therapeutically effective amount" of the drug. Even assuming *arguendo* the claim was so limited to the drug affecting programmed ribosomal frameshifting and/or nonsense-mediated mRNA decay, it is noted that this is an inherent feature of practicing the method of treating HIV by administering anisomycin as taught by JP 63146818 A. In other words, by administering anisomycin for the treatment of HIV, in accordance with the method of JP 63146818 A, ribosomal frameshifting and/or nonsense-mediated mRNA decay would have inherently been affected. MPEP 2112 makes clear that an inherent feature need not be recognized at the time of the invention. Thus, although JP 63146818 A is silent as to whether administration of anisomycin "modulates programmed ribosomal frameshifting and/or nonsense-mediated mRNA decay," absent evidence to the contrary, administration of anisomycin for treatment of HIV would have inherently had such effect(s). See MPEP 2112.02.

In response to applicants' argument that Dinman et al. was published after the earliest effective filing date of the instant application and cannot be used against the present claims, applicants' attention is directed to MPEP 2131.01, which states that an extra reference can be used to show an inherent characteristic of the thing taught by the primary reference, *i.e.,* that anisomycin is a peptidyl transferase inhibitor. Moreover, it is

noted that MPEP 2131.01, citing MPEP 2124 states, "the critical date of extrinsic evidence showing a universal fact need not antedate the filing date." Thus, the reference of Dinman et al., teaching a universal fact, *i.e.,* that anisomycin is a peptidyl transferase inhibitor, need not antedate the effective filing date of the instant application.

***Claim Rejections - 35 USC § 102/103***

**[28]** The rejection of claims 6 and 47 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over JP 63146818 A as evidenced by Dinman et al. is maintained for the reasons of record as set forth at item [12] of the Office action mailed May 14, 2004 and for the reasons stated below.

**[29]** RESPONSE TO ARGUMENTS: Applicants reiterate their argument addressing the rejection under 35 U.S.C. 102(b) above. Applicants direct the examiner's attention to newly added claim 51, asserting that claim 51 is patentable over the prior art. Applicants' arguments are not found persuasive at least for the reasons stated above.

***Conclusion***

**[30]** Status of the claims:

- Claims 1-7 and 32-56 are pending.
- Claims 7, 33, 35-43, 48-50, 52, and 54-56 are withdrawn from consideration.
- Claims 1-6, 32, 34, 44-47, 51, and 53 are rejected.
- No claim is in condition for allowance.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 7:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 872-9306. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1652